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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,389	12/05/2003	Kevin Smith	SYN-8312	9231

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EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
05/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,389	SMITH ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-89* is/are pending in the application.

4a) Of the above claim(s) *67-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-66 and 83-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 6, 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-10, 12-16, 18, 20, 21, 23-25, 27, 31-35, 38, 66, 83, 85, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldman et al. (5,237,996)

in view of Abrams (5,492,119). Waldman et al. discloses the invention substantially as claimed. Waldman et al. disclose at least in figures 1A-2B, 1; a retractor including a rigid body (44); a retraction device for manipulating or grasping an object, where the device has a head (46) connected to the distal end of the body; two, flexible needles (18) of resilient metal; and a removable actuation device (10 or 32) connected to the proximal end of the body; where the body has a longitudinal extent, where the head is connected removably or integrally formed (i.e., integrated) with the body; where the head has two head halves (i.e., the head is symmetrical with respect to a longitudinal axis and can be defined by two halves formed together) and defines curved tracks (60), each track having a concentrically curved opposing sides (pair of sides within 60 or combination of 60 and 56) and having a track exit; where the tracks exits open in a direction at a substantially orthogonal angle to the longitudinal direction, where the track exits are disposed to permit movement therethrough substantially without friction and are disposed on opposing sides of the head, where the surfaces of the tracks guide the needles in a direction substantially orthogonal to a movement direction of the actuation device and in substantially opposite directions, where the tracks have a shape corresponding to a memory shape of a portion of the needles, where the needles include a substantially linear proximal portion and an arcuate distal portion, where the arcuate shape of the portion is no greater than a circle, where the retractor includes proximal stop (36), where the actuation device (10) has a locking device (32) and an overstroke preventor (34), where the actuation device is a one-handed actuation device,

where the actuation device selectively moves an actuator (32), and where the needles are fixedly connected to the actuation device (at 32 or 38).

However, Waldman et al. do not disclose that the flexible needles are of a shape memory material having a memory shape. Abrams teaches, at least in figures 3-9 and in col. 2, lines 57-62; col. 5, lines 13-25; and col. 6, lines 54-65; retractor needles (e.g., 39 or 65) formed of a shape memory material (e.g., nickel-titanium alloy or NITINOL) having a memory shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Abrams, to form the needles in the device of Waldman et al. out of a shape memory material having a memory shape. Such a material would allow the needles to be repeatedly deformed and have good shape recovery. Additionally, Waldman et al. do not disclose that two halves of the head are removably connected to one another. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the head from two, separate halves, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

4. Claims 1, 5, 11, 15, 17, 19, 26, 36, 37, 39, 60, 88, 84, and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wittkampf (4,142,530) in view of Abrams (5,492,119) Wittkampf discloses the invention substantially as claimed. Wittkampf discloses, at least in the figures and in col. 3, lines 14-32 and col. 4, lines 48-51; a retractor including a flexible body with a coil winding (37) and an outer jacket (31); a retraction device for manipulating or grasping an object, where the device has a head (30) connected to the distal end of the body; flexible needles (40, 38-1) of a resilient

material; and an actuation device (44) connected to the proximal end of the body, where the needles include a portion of arcuate shape, where the head includes a set of curved tracks (within 35), where each track has an arcuate segment having concentrically-curved opposing sides and track exits each having a diameter at least as large as a needle diameter, where the head includes a shim (52), where a segment of the arcuate-shaped portion of a needle remains in a track while the needles are extended out of and retracted into the head, where the arcuate-shaped portion corresponds to a shape of an arcuate segment; where the needles (i.e., 40 and 38-1), when actuated, move in substantially opposite directions, where the needles are sized to control penetration depth through tissue, and where the head has an anchoring spike (38-2, another element 40 (see col. 4, lines 31-35), or the protrusions projecting from surface 35 for guiding needles 38). However, Wittkampf does not disclose the flexible needles are of a shape memory material having a memory shape. Abrams teaches, at least in figures 3-9 and in col. 2, lines 57-62; col. 5, lines 13-25; and col. 6, lines 54-65; retractor needles (e.g., 39 or 65) formed of a shape memory material (e.g., nickel-titanium alloy or NITINOL) having a memory shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Abrams, to form the needles in the device of Wittkampf out of a shape memory material having a memory shape. Such a material would allow the needles to be repeatedly deformed and have good shape recovery. Wittkampf also does not disclose that the body and retraction device are sized to fit within the working channel of an endoscope. Nevertheless, it would have been a matter of obvious design choice to size the

components of Wittkampf's device as claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being with the level of ordinary skill in the art. Additionally, Wittkampf does not disclose that the two halves of the head are removably connected to one another. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the head from two, separate halves, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

5. Claims 1, 22, 28-30, and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over King (6,745,879) in view of Abrams (5,492,119). King discloses the invention substantially as claimed. King discloses, at least in figures 1-5A and 7; a retractor including body (16); a retraction device for manipulating or grasping an object, where the device has a head (14) connected to the distal end of the body; flexible needles (32 and 33 combined) of resilient metal; and an actuation device (7) connected to the proximal end of the body; where the head defines curved tracks, each track having an arcuate segment and concentrically curved opposing sides; where the needles each have a portion with an arcuate shape (distal portion of 44 combined with 33); where the needles are slidably disposed within the arcuate segments; where the needles, upon actuation, move in substantially opposite directions, where the arcuate shape is greater than a semi-circle (see element 33 in fig. 4), where the actuation device has a rod (18) passing through the body and removably connected to the needles (via 17) or is integrally formed (i.e., assembled together) with the needles.

However, King does not disclose the flexible needles (i.e., 44) are of a shape memory material having a memory shape. Abrams teaches, at least in figures 3-9 and in col. 2, lines 57-62; col. 5, lines 13-25; and col. 6, lines 54-65; retractor needles (e.g., 39 or 65) formed of a shape memory material (e.g., nickel-titanium alloy or NITINOL) having a memory shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Abrams, to form the needles in the device of King out of a shape memory material having a memory shape. Such a material would allow the needles to be repeatedly deformed and have good shape recovery.

6. Claims 39-54, 58, 59, 61-65, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldman et al. (5,237,996) in view of Abrams (5,492,119), and further in view of Green (5,928,137). Waldman et al. in view of Abrams disclose substantially as claimed a tissue retractor including a rigid body and retraction device. However, Waldman et al. in view of Abrams do not disclose that the retractor is combined with a flexible endoscope having at least one working channel for receiving the body and the retraction device. Green teaches, at least in figures 1 and 5 and in col. 6, lines 49-65; a flexible endoscope having at least one working channel (e.g., 152) for receiving an endoscopic tool. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Green, to include a flexible endoscope with the device of Waldman et al. in view of Abrams. A flexible endoscope with at least one working channel would not only allow access for the device of

Waldman et al. in view of Abrams to a surgical site, it would also allow diagnosis and imaging of the site, especially where the site has narrow confines.

Response to Amendment

7. Applicant's arguments filed on January 21, 2009 have been fully considered but are moot in view of new grounds of rejection.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

May 5, 2009